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3696 '00 JAN -7 P2:23

December 28, 1999

Dockets Management Branch (HFA-305)

Food and Drug Administration

5630 Fisher's Lane, Rm. 1061

Rockville, Maryland 20852

To Whom It May Concern:

Regarding proposed rule "Suitability Determination for Donors of Human Cellular and Tissue-based Products" (Docket No. 97N-484S) as listed in the Federal Register, Volume 64, Number 189, September 30, 1999, pages 52696-52723, I have the following comments.

The provision recommending a six-month follow-up infectious disease testing of the donor or the donor's mother for umbilical cord donors could cause ramifications contrary to the intent of the ruling. Our IRB had some ethical questions about requiring six-month evaluation. These ethical issues will have to be addressed and resolved prior to implementation of this rule. It is commonly felt that cord cells are less likely to transmit infectious diseases than transplants obtained from other sources. Unrelated bone marrow donations from adult donors are not tested six months post donation. Would the intent of the ruling be to encourage the use of a marrow donation from an adult that is tested prior to donation over the use of a cord cell donation?

However, just as with "Donor Retested Plasma", re-testing the donor for infectious diseases some time after the donation marginally increases the safety of the product. I would recommend the agency approach the re-tested umbilical cord cell product the same way the Donor Retested Plasma has been addressed. Make it a separate product. The end user of the product can evaluate the use of one product over another based on the product label.

Also, the provision requiring the mother to be tested within 48 hours of donation needs to be changed to anytime after donation. The infectious disease tests detecting the presence of antibodies currently used will only increase in

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sensitivity with the passing of time. That is the reason the concept of testing six months post donation is valid at all. If the agency feels there is a need for a time limit, I would strongly recommend allowing at least six weeks (the normal time for a follow-up visit post-partum).

Thank you for your consideration.

Sincerely,

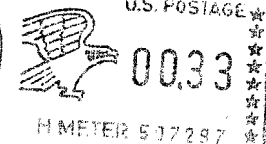
A handwritten signature in cursive script, appearing to read "Nancy Eckert".

Nancy E. Eckert, MT(ASCP)SBB  
President and CEO

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